

AUG 23 2012



**Premarket Notification [510(K)] Summary**  
(per 21 CFR 807.92)

July 2012

**Submitter:**

TranS1, Inc.  
301 Government Center  
Drive  
Wilmington, NC 28403

**Contact Person:**

Cheryl L Wagoner  
Director of Regulatory  
910-332-1703 (phone), 910-233-1701 (fax)

**Proprietary Name:**

TranS1® Interbody Fusion System

**Classification:**

888.3080: Intervertebral Fusion Device (MAX)

**Predicate Device:**

Life Spine Plateau Spacer System: K111569

**Indications and Intended use:**

The TranS1 Interbody Fusion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The TranS1 Interbody Fusion System is designed to be used with autogenous bone graft and a supplemental spinal fixation system that is cleared for use in the lumbar spine.

**Device Description**

The TranS1® Interbody Fusion System is a radiolucent PEEK interbody fusion implant comprised of various heights and footprints to accommodate individual patient anatomy and graft material size. It also interfaces with Class I access instruments and disc preparation instruments. The TranS1® Interbody Fusion System provides anterior, transforaminal or posterior approaches to the spine. The access techniques allow a large cage to be implanted similar to marketed anterior, transforaminal, or posterior lumbar interbody fusion devices. It is designed for use with supplemental fixation to provide structural stability in skeletally mature individuals.

**Technological Characteristics and Substantial Equivalence**

Documentation was provided to demonstrate that the TranS1® Interbody Fusion System is substantially equivalent to the Predicate Life Spine Plateau Spacer System (K111569). The Subject device is substantially equivalent to the Predicate devices in intended use, level of attachment, materials, labeling, sterilization, and technological characteristic. These devices

have the same intended use and indications and rely on the same fundamental scientific technology; therefore the Subject device is substantially equivalent to the Predicate devices.

### Summary of Testing

Mechanical testing for the TranS1 Interbody Fusion System was performed per ASTM standards and included:

Test	Standard
Static Compression	ASTM F2077-11
Static Compression Shear	ASTM F2077-11
Static Torsion	ASTM F2077-11
Subsidence	ASTM F2267-04
Expulsion	N/A
Dynamic Compression	ASTM F2077-11

All static and dynamic testing met or exceeded the requirements as established by the test protocol and applicable ASTM standards. The results demonstrated that the subject TranS1 Interbody Fusion System presents no new worst-case for performance testing, and the subject device was therefore found to be substantially equivalent to the predicate.

### Conclusion

Based on the indications for use, technological characteristics, and comparison to predicate device, the subject TranS1 Interbody Fusion System has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Trans1 Incorporated  
% Ms. Cheryl L Wagoner  
Director of Regulatory  
301 Government Center Drive  
Wilmington, North Carolina 28403

AUG 23 2012

Re: K120991  
Trade/Device Name: TranS1<sup>®</sup> Interbody Fusion System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: May 23, 2012  
Received: July 23, 2012

Dear Ms. Wagoner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

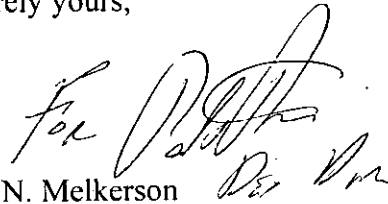
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "For Mark N. Melkerson".

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Device  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Statement of Indications for Use

510(k) Number: K120991

Device Name: TranS1® Interbody Fusion System

### Indications for Use:

The TranS1 Interbody Fusion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The TranS1 Interbody Fusion System is designed to be used with autogenous bone graft and a supplemental spinal fixation system that is cleared for use in the lumbar spine.

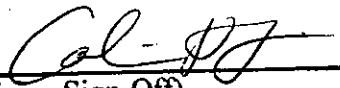
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K120991